REMARKS

Assignee and the undersigned attorney thank Examiner Shaffer for his review of this patent application. Claims 1, 3-5, 18, 25, 29, 30, 33, and 34 are amended above; claims 2, 36, and 41 are cancelled; and claims 44-48 are added. Twenty-six total claims are now pending. Assignee respectfully requests reconsideration of pending claims 1, 3-5, 17-21, 23-25, 28-34, 42, and 43 and consideration of new claims 44-48.

Request for Interview

Assignee requests that the Examiner contact the undersigned attorney to schedule a telephone interview prior to the mailing of a first office action in the continued examination of this application if the Examiner does not believe all claims are allowable after considering the request for continued examination and the claim amendments and remarks below.

Claim Rejections Under 35 U.S.C. § 103 in View of *Faccioli* Combined with *Lee*

The Action rejected claims 1-5, 17, 30-34, 36, and 41 under 35 U.S.C. § 103 as being unpatentable over PCT Publication No. WO 00/40163 to *Faccioli et al.* ("*Faccioli*") in view of U.S. Patent No. 5,405,347 to *Lee et al.* ("*Lee*"). Claims 2, 36, and 41 are cancelled, and no new claims dependent from independent claims 1 and 30 have been added.

Claims 1, 3-5, 17, and 34

In the December 19, 2006 office action in this application, the Examiner rejected claim 1 as anticipated by *Faccioli*. (*See* 12/19/06 Action, p. 3.) Following a telephone interview on March 22, 2007 and a minor modification to claim 1, the Examiner rejected claim 1 as obvious in view of *Faccioli* combined with *Lee*. (*See* 6/22/07 Action, p. 2.) Assignee clearly explained why claim 1 is not anticipated by *Faccioli* (*see* 4/12/07 Response,

pp. 14-15), and the Examiner agreed and set forth the new § 103 rejection. However, the Examiner's rejection lacks clarity and cannot be fully understood given his assertion that *Faccioli* discloses all of the elements of claims 1-5, 17, 30-34, 36, and 41 "except for carriage having two threaded holes . . ." because this claim limitation identified by the Examiner in the rejection was previously present only in claim 4, and not in claim 1. (*See* 6/22/07 Action, pp. 2-3.)

In any event, Assignee has amended claim 1 in an effort to further prosecution and distinguish the claim from *Faccioli* and *Lee*. Amended claim 1 (in clean form) now recites:

> An external fixation apparatus comprising:
> a pivot arm comprising:
> an upper portion with a ball end and a second opposite end having a first recess formed therein;
> a lower portion with a prong end and a second opposite end having a recess formed therein, wherein the lower portion and upper portion are secured together with the first and second recesses adjacent one another to form an internal recess in the pivot arm;
> a carriage within the internal recess of the pivot arm such that a position of one of the upper and lower portions of the pivot arm with respect to a longitudinal axis of the pivot arm is adjusted when the carriage is moved; and
> a pin clamp coupled to and rotatable about the prong end of the pivot arm through a lockable joint, the pin clamp being attachable to a bone segment.

The pivot arm of *Faccioli* is not formed of upper and lower portions with first and second recesses that are adjacent to one another to form an internal recess in the pivot arm, as recited in amended claim 1. Moreover, the Examiner admits that *Faccioli* does not teach a carriage (Action, p. 2), and *Faccioli* clearly fails to teach or suggest a carriage (or any structure) within the internal recess of the pivot arm such that one of the upper and lower portions of the pivot arm is adjusted when the carriage is moved.

Lee does not teach a pivot arm or a pin clamp, as the Examiner has previously acknowledged, but, in the Action, the Examiner suggests that *Lee* teaches the importance of lateral movement in allowing a surgeon to realign a fixation device and describes a worm gear used in a connector of external fixator rods, therefore rendering all of claim 1 (and other claims) obvious. However, the teaching of a worm gear in the rod connector of *Lee* does not describe or suggest a carriage, and the Examiner does not identify any portion of *Lee* that describes the carriage recited in amended claim 1. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. The Examiner's rejection of claim 1 must be withdrawn because neither *Faccioli* nor *Lee* describe or suggest, alone or in combination, a carriage within an internal recess of a pivot arm, where movement of the carriage adjusts the position of one of the upper and lower portions of the pivot arm and where the internal recess is formed by recess in adjacent ends of the upper and lower portions that are secured together to form the pivot arm.

Inasmuch as claims 3-5, 17, and 34 depend from and thereby include the limitations of amended claim 1, claims 3-5, 17, and 34 should also be allowed for at least such dependencies. Claims 3-5 and 34 should also be allowed for the following additional reasons.

Because *Faccioli* and *Lee* fail to teach or suggest the carriage of claim 1, they also fail to teach or suggest the additional limitations concerning the carriage that are recited in claim 3. More specifically, *Faccioli* and *Lee* do not describe a carriage positioned entirely within the internal recess of the pivot arm that is externally accessible from the upper portion of the

pivot arm for fine adjustment in one axis and from the lower portion for fine adjustment in a second, isolated axis.

Additionally, claim 4 requires keybolts to operate each of two worm gears, but the Examiner does not identify any structure in *Faccioli*, *Lee*, or anywhere else in the art that teaches or suggests the recited keybolts. Claim 5 recites that the pivot arm has only a single prong at the prong end of the lower portion; however, *Faccioli* only teaches a pivot arm with a bifurcate end, and *Lee* also fails to teach this structure because it does not teach any type of pivot arm. Finally, claim 34 recites the pin clamp further comprises a push/pull mechanism having at least one end externally accessible during use for releasably coupling the pin clamp to the pivot arm, but pivot 35 of *Faccioli* (which the Examiner states in one interpretation is a push/pull mechanism) has its ends permanently fixed between prongs 23, 24 of bifurcate end 21 of stem 20 during use of the stem 20 and tilting clamp 25. As such, pivot 35 cannot fairly be said to be a push/pull mechanism, as it cannot be pushed or pulled during use of the device and it does not have any ends that are accessible for such use.

For the above additional reasons, claims 3-5 and 34 should be allowed.

Claims 30-33

Amended claim 30 (in clean form) recites:

> A method of treating a skeletal condition or injury using an external fixation apparatus, the method comprising:
>
> (a) fixing a first member to a first side of a fracture with upper bone pins;
>
> (b) fixing a pin clamp to a second side of the fracture with lower bone pins;
>
> (c) providing a pivot arm comprising an upper portion with a ball end and a second end opposite the ball end with a first recess formed in the second end and a lower portion with a prong end and a second end

opposite the prong end with a second recess formed in the second end, where the upper and lower portions are secured together with the first and second recesses adjacent one another to form an internal recess in the pivot arm;

(d) coupling the pin clamp to the first member through the use of a pivot arm, wherein the lower portion of the pivot arm is coupled directly to the pin clamp; and

(e) moving a carriage within the internal recess of the pivot arm to adjust a position of one of the upper and lower portions of the pivot arm with respect to a longitudinal axis of the pivot arm.

For reasons similar to those described above with respect to apparatus claim 1, *Faccioli* and *Lee*, alone or in combination, do not teach or suggest each and every element of amended method claim 30, and thus the Examiner has failed to establish the *prima facie* obviousness of claim 30. More specifically, the cited references do not teach or suggest providing the pivot arm as recited in 30(c) or moving a carriage within the internal recess of the pivot arm as set forth in 30(e). For these reasons, the Examiner should withdraw the rejection of claim 30 in view of *Faccioli* and *Lee*, and claim 30 should be allowed.

Inasmuch as claims 31-33 depend from and thereby include the limitations of amended claim 30, claims 31-33 should also be allowed for at least such dependencies. Claim 33 should also be allowed because *Faccioli* and *Lee* do not teach or suggest moving a carriage to cause both (i) the upper portion of the pivot arm to move in one axis with respect to the longitudinal axis of the pivot arm and (ii) the lower portion of the pivot arm to move in a second axis with respect to the longitudinal axis of the pivot arm that is isolated from the first axis, as recited in amended claim 33.

Claim Rejections Under 35 U.S.C. § 103 in View of *Pennig* Alone or *Pennig* Combined with *Lee* and/or *Hoffman*

The Action rejected claims 25 and 29 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,827,282 to *Pennig* ("*Pennig*"). The Action rejected claims 18-21, 23, and 28 under 35 U.S.C. § 103(a) as being unpatentable over *Pennig* in view of *Lee*. Finally, the Action rejected claims 24, 42, and 43 under 35 U.S.C. § 103(a) as being unpatentable over *Pennig* in view of *Lee* and in further view of U.S. Patent Application Publication No. 2002/0077629 to *Hoffman et al.* ("*Hoffman*"). New claims 44-48, which depend from claim 25, have been added.

Claims 25, 28, 29, and 42-48

Amended claim 25 recites:

> 25. (Currently Amended) An external fixation system for attaching pins or wires to at least one bone segment, the system comprising:
> a first member;
> a second member coupled to the first member, the second member comprising a shaft that extends transversely from an end portion of the second member and has a groove extending substantially around a circumference of the shaft; and
> a pin clamp attachable to and detachable from ~~snap-fit onto~~ the shaft of the second member, the pin clamp comprising:
> a first jaw and a second jaw;
> a hole in the first jaw configured to receive the shaft; and
> a push or pull mechanism that is positioned within the first jaw and is externally accessible for manual manipulation during use of the pin clamp, the push or pull mechanism comprising a locator pin that is received within the groove of the shaft when the ~~pivot arm~~ second member and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the ~~pivot arm~~ second member.

As an initial matter, the Examiner identified rotary joint 11 of *Pennig* as allegedly teaching the second member/pivot arm recited in claims 25 and 18 (respectively), but it is unclear how

the entire joint of *Pennig* represents the second member/pivot arm as the Examiner has not identified the recited end portions of the second member/pivot arm, or how the shank portion 6 of *Pennig* extends transversely from the end portion of the pivot arm as recited in claims 25 and 18. In any event, *Pennig* fails to teach or suggest several limitations of amended claim 25, and thus the Examiner has not established the *prima facie* obviousness of claim 25.

Most significantly, *Pennig* does not teach or suggest "a push or pull mechanism that is positioned within the first jaw and is externally accessible for manual manipulation during use of the pin clamp, the push or pull mechanism comprising a locator pin that is received within the groove of the shaft when the second member and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the second member," as recited in amended claim 25.

The pin 16 inserted into groove 15 in *Pennig* is permanently located within half shell 3 to ensure axial retention of shaft 6 within the half shell 3. Half shell 3 rotates about axis 8, but there is no teaching or suggestion in *Pennig* that pin 16 is removable at any time from groove 15 to disengage half shell 3 from stem 6 or for any other purpose. Moreover, there is no teaching or suggestion in *Pennig* that pin 16 is (or forms any part of) a push or pull mechanism that is externally accessible for manual manipulation during use of the *Pennig* device. Fig. 2A of *Pennig* clearly shows that no part of pin 16 extends outside the body of half shell 3 and that pin 16 is not externally accessible for manual manipulation during use of half shell 3. The Examiner's reliance on an internal, permanently secured pin, such as pin 16 of *Pennig*, to reject claim 25 is misplaced, and *Pennig* clearly fails to teach or suggest teach a push or pull mechanism as explicitly recited in amended claim 25. Moreover, because half

shell 3 and shaft 6 are permanently secured to one another, *Pennig* clearly fails to teach or suggest a pin clamp attachable to and detachable from the shaft of the second member as recited in claim 25.

For at least the above reasons, the Examiner has failed to establish a *prima facie* basis for unpatentability of claim 25, and therefore the rejection of claim 25 should be withdrawn.

Inasmuch as claims 28, 29, and 42-47 depend from and thereby include the limitations of amended claim 25, claims 28, 29, and 42-47 should also be allowed for at least such dependencies. Claims 28, 29, and 44-48 should also be allowed for the following additional reasons.

The Examiner alleges that it would have been obvious to use the worm gears of *Lee* in the *Pennig* device in the portion corresponding to the ball-joint connection 7 to form the invention recited in claim 28 where the second member has two end portions that may be translated transversely to one another relative to a longitudinal axis of the second member in at least two dimensions. However, as mentioned above with respect to claim 25, it is unclear what the Examiner believes are the end portions of the recited second member as the Examiner identified the entire rotary joint 11, and not any particular structure(s), as the "second member." Shaft 6 of *Pennig* is fixed within half shell 3, and thus it is not seen how this component could move with respect to the longitudinal axis that runs through rotary joint 11. In short, the Examiner's stated rejection does not establish a *prima facie* case of obviousness for claim 28.

Claim 29 further recites that the locator pin is pulled manually by the user to allow for release of the shaft from the pin clamp. Examining the drawings of *Pennig*, Fig. 2A in particular, it is clear that pin 16 cannot be pulled manually by a user, as recited in claim 29.

New claims 44-47 each depend from claim 25 and recite the following additional limitations:

- the locator pin further comprises an enlarged knob end that is manually pulled to remove an opposite end of the locator pin from the groove of the shaft (claim 44);
- the push or pull mechanism further comprises a biasing element that surrounds a portion of the locator pin (claim 45);
- the pull or pull mechanism further comprises a button to which a first end of the locator pin is connected such that a second opposite end of the locator pin moves out of the groove of the shaft when the button is manually depressed (claim 46); and
- the locator pin is biased by a spring into a position to interfere with the groove of the shaft when the shaft is inserted into the hole of the first jaw (claim 47).

Neither *Pennig* nor any of the other references cited by the Examiner teach or suggest, alone or in combination, any of these additional limitations. In particular, there is no enlarged knob on or any button connected to an end of pin 16 of *Pennig*; nor is pin 16 biased into position or a biasing element used around a portion of pin 16. Even if taught elsewhere in the art, one skilled in the art would not add these features to *Pennig* because pin 16 of *Pennig* is designed to be permanently placed into half shell 3 to permanently engage groove 15 of shank 6, and thus there is no reason, motivation, or suggestion to add any of the recited features that are useful in accessing and moving the recited locator pin of the pin clamp to releasably engage the groove of the shaft of the second member. Furthermore, none of the

other cited references teach or suggest the recited features to be used in conjunction with a push or pull mechanism with a locator pin that engages a groove.

With respect to claim 48, the Examiner admits that *Pennig* does not teach a snap-fit connection between the pin clamp and the pivot arm (the pin does not snap fit into the groove, in the Examiner's words) (*see* 6/22/07 Action, p. 4), but the Examiner asserts that it would have been obvious to modify *Pennig* so that the pin clamp and pivot arm snap fit together to provide a surgeon with an audible and tactile response to confirm that a stable connection between the two components has been made.

However, the Examiner is ignoring that the alleged pin clamp of *Pennig* (item 3 in Figs. 1 and 2) and shaft (item 6) of the alleged pivot arm are not releasably coupled to one another, but are permanently secured to each other. There is no teaching that the half shell 3 and shank portion 6 of *Pennig* are separable from one another (absent complete destruction of the device, which is irrelevant here), and, because the two components are permanently secured prior to use by the surgeon, there is no motivation to modify *Pennig* in any manner to provide a snap fit connection as the Examiner suggests would benefit a surgeon during use because the audible and tactile response the Examiner asserts is desirable serves no purpose for two components permanently secured together.

For the above additional reasons, claims 28, 29, and 44-48 should be allowed.

Claims 18-21, 23, and 24

Amended claim 18 (in clean form) recites:

> An external fixation apparatus comprising:
> a pivot arm comprising a first end portion and a second end portion, the second end portion comprising a shaft with a free end extending

> transversely from and maintaining a fixed spatial relationship with the second end portion of the pivot arm, the shaft comprising a groove extending substantially around a circumference of the shaft, and wherein the first and second end portions are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm; and
>
> a pin clamp attachable to a bone segment and releasably attachable to and rotatable about the shaft extending from the pivot arm, the pin clamp comprising:
>
> a first jaw and a second jaw, the first jaw including a hole that receives the shaft; and
>
> a locator pin positioned within the first jaw such that the locator pin is externally accessible for manual manipulation during use of the pin clamp via a pushbutton coupled to an end of the locator pin or an enlarged knob on an end of the locator pin, wherein the locator pin is received within the groove of the shaft when the pivot arm and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm.

Claim 18 recites limitations similar, but not identical, to those recited in independent claim 25, as well as dependent claim 28. For reasons similar to those described above with respect to claims 25 and 28, claim 18 should also be allowed. More particularly, *Pennig* and *Lee*, either alone or in combination, do not teach or suggest at least "a locator pin positioned within the first jaw such that the locator pin is externally accessible for manual manipulation during use of the pin clamp" and that "the first and second end portions [of the pivot arm] are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm."

Claim 18 should also be allowed for the following additional reasons. Claim 18 requires that the locator pin is externally accessible via "a pushbutton coupled to an end of the locator pin or an enlarged knob on an end of the locator pin." As discussed above with respect to claims 44 and 46, a pushbutton and an enlarged knob are not described or suggested by *Pennig* or any other references cited by the Examiner. Claim 18 also requires

that the shaft of the pivot arm (to which the pin clamp is coupled) have "a free end extending transversely from and maintaining a fixed spatial relationship with the second end portion of the pivot arm." The Action identifies shank 6 of *Pennig* as corresponding to the recited shaft, but shank 6 does not maintain a fixed spatial relationship to the end portion of the structure from which it extends, as shown clearly in Figs. 1 and 2 of *Pennig*.

For all of the above reasons, the Examiner should withdraw the rejection of claim 18 and claim 18 should be allowed.

Inasmuch as claims 19-21, 23, and 24 depend from and thereby include the limitations of claim 18, claims 19-21, 23, and 24 should also be allowed for at least such dependencies. Claims 19-21 should also be allowed for the following additional reasons.

Claims 20 and 21 should be allowed for reasons similar to those described above with respect to claims 4 and 29, respectively. Claim 19 should also be allowed because the Examiner has not established a *prima facie* case of obviousness of this claim. Contrary to the Examiner's assertions, it would not have been obvious to extend half shell 2 such that bolt 17 passes through half shell 2, and it is entirely unclear how one would extend half shell 2 with half shell 3 (as currently configured) such that bolt 17 would extend through both half shells 2 and 3. If half shell 2 were extended vertically, then it would not be necessary for half shell 3 to extend over horizontally at its top end (as shown in Figs. 1 and 2 of *Pennig*), and bolt 17 would pass through only half shell 2 and no longer half shell 3. Moreover, if half shell 2 were extended vertically, then shank 6 of rotary joint 11 would no longer fit within just half shell 3, but instead would be captured between half shells 2 and 3, requiring additional parts and more complexity than having shank inserted into a single component as

in *Pennig*. The Examiner has offered no drawing, explanation, or meaningful reason how or why this "design choice" would be accomplished and still meet all of the limitations of claim 19 and claim 18 from which it depends.

For the above additional reasons, claims 19-21 should be allowed.

Conclusion

The foregoing, along with a Request for Continued Examination, is submitted as a full and complete response to the Action mailed June 22, 2007. Assignee submits that claims 1, 3-5, 17-21, 23-25, 28-34, and 42-48 are in condition for allowance, and notice of allowance is respectfully requested. The preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability. If the Examiner believes there are any issues that can be resolved via a telephone conference, or there are any informalities that can be corrected by an Examiner's amendment, please call Geoffrey Gavin at (404) 815-6046.

Other than the fees for the Request for Continued Examination being submitted concurrently herewith and the one-month extension of time, the undersigned attorney believes no further fees are due; however, the Commissioner is authorized to debit deposit account no. 11-0855 to the extent necessary if fees are due.

Respectfully submitted,

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